

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

**NABI BIOPHARMACEUTICALS,  
Plaintiff,**

**v.**

**ROXANE LABORATORIES, INC.,  
Defendant.**

**Case No. 2:05-CV-889  
JUDGE EDMUND A. SARGUS, JR.  
Magistrate Judge Terence P. Kemp**

**OPINION AND ORDER**

This matter is before the Court for consideration of the Plaintiff's Motion to Dismiss Defendant's Counterclaim or, in the alternative, to Sever and Stay. (Doc. #47). For the reasons that follow, the motion is denied.

**I.**

Plaintiff, Nabi Biopharmaceuticals ["Nabi"], brings this action seeking declaratory and injunctive relief for alleged patent infringement under Section 271(e) of the Patent Act, 35 U.S.C. § 271(e)(2)(A), against Defendant Roxane Laboratories, Inc. ["Roxane"]. The action arises as a result of Roxane's submission of an Abbreviated New Drug Application to the Food and Drug Administration ["FDA"] for approval to market a generic version of Nabi's PhosLo capsules. The Court has jurisdiction pursuant to 28 U.S.C. § 1331.

Nabi is the innovator of a product called PhosLo, a prescription drug used to treat

hyperphosphatemia<sup>1</sup>. Nabi holds three patents for PhosLo: Patent No. 4,879,105 (the “105 patent”); Patent No. 6,576,665 (the “665 patent”); and Patent No. 6,875,445 (the “445 patent”). The 105 patent is scheduled to expire in April 2007. The 665 patent will expire on April 3, 2021. In its Amended Complaint, Nabi alleges that Roxane’s submission to the FDA of an Abbreviated New Drug Application [“ANDA”] constitutes an act of infringement of the 665 patent because “Roxane included within its ANDA a paragraph IV certification to the effect that the 665 patent was invalid or would not be infringed by Roxane’s proposed generic copy of Nabi’s successful drug.” (*Am. Compl.* at ¶ 9). Nabi alleges that, upon gaining FDA approval, Roxane will engage in the commercial manufacture, use and sale of the calcium acetate capsules and that this will infringe the 665 patent as well as the 445 patent. (*Id.* at ¶¶ 10-21).

In its Amended Answer and Counterclaim, Roxane alleges that Nabi has “a monopoly on the sale of calcium acetate capsules.” (*Counterclaim* at ¶ 5). Roxane further asserts that its ANDA included a “Paragraph III” certification regarding the 105 patent, stating that Roxane did not seek approval of its generic calcium acetate product until after the 105 patent expires in April 2007. (*Id.* at ¶ 10). Roxane claims that it notified Nabi of its request for ANDA approval and its certification that the 665 patent would not be infringed because “the claims of the 665 patent require calcium acetate with a bulk density of between about 0.55 kg/L and about 0.75 kg/L, whereas the calcium acetate of Roxane’s proposed product has a bulk density outside of the claimed range.” (*Id.* at ¶ 12). Roxane claims that “[p]rior to the commencement of this action Roxane provided Nabi with clear evidence that Roxane’s proposed generic calcium acetate

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<sup>1</sup>Hyperphosphatemia involves an excess of phosphorous, usually associated with chronic kidney failure.

capsules do not infringe either the 665 patent or the 445 patent.” (*Id.* at ¶ 15).

Roxane’s Counterclaim consists of four counts: Declaratory Judgment for nonfringement of Nabi’s patents (Count I); Attempted Monopolization (Count II); Inequitable Conduct as to the 665 Patent (Count III); and Inequitable Conduct as to the 445 Patent (Count IV). With respect to Count II, Roxane alleges, in part:

Nabi’s lawsuit is objectively baseless in that, *inter alia*, Roxane’s proposed calcium acetate capsules are made from calcium acetate with a bulk density outside of the range claimed in the 665 and 445 patents and utilize untabletted powder within a capsule rather than calcium acetate that has been compressed to create a “caplet within a capsule” as required by the claims of the 665 and 445 patents.

On information and belief, Nabi filed this sham lawsuit against Roxane in an improper effort to retain and/or obtain monopoly power in this market . . . .

(*Id.* at ¶¶ 51-52). Roxane alleges that Nabi’s actions violate Section 2 of the Sherman Act, 15 U.S.C. § 2, and entitle Roxane to relief pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15.

## II.

A motion to dismiss for failure to state a claim pursuant to Fed R. Civ. P. 12(b)(6) “should not be granted unless it appears beyond a doubt that the plaintiff can prove no set of facts in support of his claim that would entitle him to relief.” *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). All well-pleaded allegations must be taken as true and be construed most favorably toward the non-movant. *Schuer v. Rhodes*, 416 U.S. 232, 236 (1974); *Mayer v. Mylod*, 988 F.2d 635, 637 (6<sup>th</sup> Cir. 1993). While a court may not grant a Rule 12(b)(6) motion based on disbelief of a complaint’s factual allegations, *Lawler v. Marshall*, 898 F.2d 1196, 1199 (6<sup>th</sup> Cir. 1990), the court “need not accept as true legal conclusions or unwarranted factual inferences.” *Morgan v.*

*Church's Fried Chicken*, 829 F.2d 10, 12 (6<sup>th</sup> Cir. 1987). Consequently, a complaint will not be dismissed pursuant to Rule 12(b)(6) unless there is no law to support the claim made, the facts alleged are insufficient to state a claim, or there is an insurmountable bar on the face of the complaint.

### III.

#### A. Motion to Dismiss.

Nabi moves for dismissal of Roxane's antitrust counterclaim on two grounds: (1) Roxane has failed to plead sufficient facts to overcome the presumption that Nabi is immune from antitrust liability under the *Noerr-Pennington* doctrine; and (2) Roxane has failed to plead the specific elements required for an antitrust counterclaim.

#### 1. *Noerr-Pennington* Doctrine

The *Noerr-Pennington* doctrine operates to shield from antitrust liability those who petition the government. *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *Mine Workers v. Pennington*, 381 U.S. 657 (1965). This immunity has been applied to the initiation and prosecution of a claim for patent infringement. See *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) (extending the "philosophy" of *Noerr* and *Pennington* to "the approach of citizens or groups of them to administrative agencies ... and to courts"). In the context of patent claims, there are exceptions to the *Noerr-Pennington* doctrine, specifically for "sham" litigation and "*Walker Process* fraud." With regard to the former, immunity does not apply to petitioning that is mere "sham." With regard to

the latter, immunity does not apply to conduct before the Patent Office that is materially fraudulent. *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965). Nabi argues that Roxane has failed to plead facts sufficient to come within either the sham litigation or fraud exceptions to immunity.

### **Sham Litigation Exception**

In *Noerr*, the Supreme Court observed that immunity may be withheld when petitioning conduct is a “mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.” 365 U.S. at 144. The Supreme Court has established the following test for “sham” litigation:

First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.'

*Professional Real Estate Investors v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993), quoting *Noerr*, 365 U.S. at 144.

In support of its Motion to Dismiss, Nabi asserts that “Roxane has done nothing more than plead facts in support of a theory of literal non-infringement and has pled no facts in support of its objective baselessness allegation.” (*Motion to Dismiss* at 6). Roxane maintains that its Amended Counterclaim contains facts sufficient to support the sham exception. In particular, Roxane points to the following allegations:

On August 8, 2005, Roxane mailed notification to Nabi that Roxane had filed an ANDA seeking approval to market a generic version of Nabi's calcium acetate capsules and certifying that the 665 patent would not be infringed by Roxane's proposed product. Roxane's notification explained that its calcium acetate product would not infringe the 665 patent because the claims of the 665 patent require calcium acetate with a bulk density of between about 0.55 kg/L and about 0.75 kg/L, whereas the calcium acetate of Roxane's proposed product has a bulk density outside of the claimed range.

In light of this difference and in an effort to order to avoid [*sic*] any unnecessary legal action, Roxane subsequently provided Nabi with information, documentation, and samples regarding its proposed generic calcium acetate capsules which demonstrated that Roxane's proposed calcium acetate capsules are made from calcium acetate with a bulk density outside of the range claimed in the 665 patent and utilizing untabletted powder within a capsule, not compressed into a caplet as required by the claims of the 665 patent.

Despite knowing that Roxane's proposed generic calcium acetate product would not infringe any claim of the 665 patent, Nabi brought and has continued to maintain the current action against Roxane. Further, in Nabi's First Amended Complaint for Patent Infringement, Nabi has now asserted that Roxane's proposed calcium acetate product will also infringe U.S. Patent No. 6,875,445 (the 445 patent). The 445 patent is not listed as part of the Orange Book's entry for calcium acetate capsules.

Nabi's addition of the 445 patent to this action continues Nabi's meritless assertions that Roxane's proposed calcium acetate product infringes patent claims requiring calcium acetate with a bulk density of between 0.55 and 0.75 kg/L and/or calcium acetate that has been compressed into a caplet for insertion into a capsule. Prior to the commencement of this action, Roxane provided Nabi with clear evidence that Roxane's proposed generic calcium acetate capsules do not infringe either the 665 patent or the 445 patent.

Nabi has refused to provide Roxane with the results of any analysis done on the sample of Roxane's product provided to Braintree for testing prior to Nabi's commencement of this action and Nabi's analysis of the documents Roxane provided to it. On information and belief, Nabi has refused to provide this information because it establishes that Nabi's infringement claims are objectively baseless.

On information and belief, Nabi's true purpose in maintaining its claim that Roxane's proposed calcium acetate capsules infringe the 665 patent and in alleging that Roxane's proposed calcium acetate capsules will infringe the 445

patent is to prevent Roxane from promptly introducing its generic calcium acetate product upon the expiration of the 105 patent.

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As set forth herein, Nabi's lawsuit is objectively baseless in that, *inter alia*, Roxane's proposed calcium acetate capsules are made from calcium acetate with a bulk density outside of the range claimed in the 665 and 445 patents and utilize untabletted powder within a capsule rather than calcium acetate that has been compressed to create a "caplet within a capsule" as required by the claims of the 665 and 445 patents.

(Counterclaim at ¶¶ 12-17, 51).

The Court concludes that the foregoing allegations with respect to the "sham litigation" exception to *Noerr-Pennington* immunity are sufficient to survive the Rule 12(b)(6) motion. Contrary to Nabi's argument, the counterclaim does more than simply plead a theory of non-infringement. As noted by the court in *Skinder-Strauss Associates v. Massachusetts Continuing Legal Educ., Inc.*, 870 F.Supp. 8, 10 (D. Mass. 1994), "[b]ecause [the] counterclaims allege that the lawsuit filed . . . is objectively baseless and conceals an attempt to interfere directly with the business relationships of a competitor, the counterclaims adequately state a claim and should not be dismissed under Fed.R.Civ.P. 12(b)(6)."

### **Fraud Exception**

In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 174 (1965), the Supreme Court held that "the enforcement of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act." The Court explained:

A patent by its very nature is affected with a public interest ... [It] is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore,

give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.

*Id.* at 177. In *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998), the Federal Circuit held that *Walker Process* provides an “alternative” legal theory, which may strip a patentee of immunity independently of or in addition to the sham litigation exception. “[E]ither or both may be applicable to a particular party’s conduct . . . .” *Id.* at 1071. In order to establish *Walker Process* fraud, the claimant must show, by clear and convincing evidence: (1) a misrepresentation or omission, (2) made with intent to deceive the Patent Office, (3) on which the Patent Office justifiably relied, and (4) but for which the patent would not have issued. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir.1998); *Nobelpharma*, 141 F.3d at 1070-71, 1073. “*Walker Process* fraud is a more serious offense than inequitable conduct” and “requires higher threshold showings of both intent and materiality.” *Nobelpharma*, 141 F.3d at 1070. The claimant must also show that the party asserting the patent was aware of the fraud when it brought suit. *Id.* at 1069.

In moving to dismiss the counterclaim, Nabi contends that Roxane “has alleged nothing more than run-of-the-mill inequitable conduct . . . .” (*Motion to Dismiss* at 8). Roxane disputes this argument, pointing to ¶¶ 18-40 of its Counterclaim. In particular, with respect to the 665 patent, Roxane alleges:

Braintree<sup>2</sup> failed to disclose to the PTO a variety of facts, including its prior art PhosLo tablets (which had been on sale in the United States for several years prior to the 665 patent application), that its tablets possessed the same bulk density of

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<sup>2</sup>The 665 patent was originally obtained by Braintree in 1990. Braintree made and sold calcium acetate tablets in the United States under the trademarked name PhosLo, until Braintree assigned the 665 patent to Nabi on August 3, 2003. (*Counterclaim* at ¶¶ 18-19).



naturally occurring calcium acetate to form a calcium acetate composition as the composition described in the claims of the 665 patent application, and that its tablets had the same pharmaceutically acceptable performance (*i.e.*, “demonstrated comparable dissolution to the approved tablet formulation”). In other words, Braintree withheld from the PTO the information that it made and sold calcium acetate tablets that met nearly all of the elements of the claimed composition, including “critical” bulk density limitation, more than one year prior to the filing of the 949 application.

(*Counterclaim* at ¶ 32). Roxane claims that the patent Examiner allowed the amended claims of the 665 patent to be issued because of “Applicant’s arguments asserting that the bulk density of calcium acetate is . . . a chosen critical element of the present invention and amendments limiting the claims to the compression of calcium acetate to form a caplet.” (*Id.* at ¶ 31). Roxane asserts that its allegations are more than allegations of mere inequitable conduct.

The Court concludes, with respect to the 665 patent, that Roxane has pled facts sufficient to state a claim based on the fraud exception to *Noerr-Pennington* immunity. Roxane’s Amended Counterclaim details the various facts leading to Braintree obtaining the 665 patent as well as facts alleged to constitute fraud in obtaining the patent. Whether Roxane will come forward with sufficient evidence to support the allegations, of course, is a matter the Court cannot resolve at this juncture. The Court does conclude, however, that the allegations are sufficient to survive Nabi’s Rule 12(b)(6) motion.

The Court reaches the same conclusion regarding the 445 patent. Roxane alleges detailed facts regarding the conduct in procuring the 445 patent. (*Counterclaim* at ¶¶ 33-40). Roxane alleges:

On information and belief, at the time Nabi prepared and submitted the July 29, 2004 response to the PTO, Nabi was aware that PosLo tablets that contain a dosage amount equivalent to 667 mg of calcium acetate, anhydrous basis, had been on the market well before April 30, 2000. On information and belief, Nabi

was also aware that PosLo tablets were made with the same formulation as the claimed caplets (*i.e.*, using calcium acetate of the same bulk density) and that the two dosage forms have comparable dissolution properties. Nabi did not disclose such information about PhosLo tablets to the PTO during the prosecution of the 598 application.

(*Counterclaim* at ¶ 39). In reading Roxane's allegations as to the 445 patent in their entirety, the Court finds that the fraud exception is pled sufficiently to survive Nabi's Rule 12(b)(6) motion.

## **2. Attempted Monopolization**

Nabi also moves to dismiss Roxane's counterclaim on the basis that Roxane fails to plead the necessary elements for the claim. To plead a claim for attempted monopolization under Section 2 of the Sherman Act, Roxane must allege facts with respect to the following elements: "(1) the defendant engaged in anticompetitive conduct; (2) the defendant had a specific intent to monopolize; and (3) defendant's conduct had a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). Further, to determine whether a dangerous probability of achieving monopoly power exists, the antitrust plaintiff must define the relevant market and prove "a realistic possibility that the defendant[ ] could achieve monopoly power in that market." *Id.* at 459.

Nabi argues that Roxane's pleading of the claim for attempted monopolization is deficient for several reasons. First, Nabi argues that Roxane has failed to properly plead that Nabi has a dangerous probability of achieving monopoly power. Second, Nabi argues that Roxane has failed to define the relevant market in its pleading because it identifies at least three markets: (1) the market for calcium acetate capsules (*Counterclaim* at ¶ 5); (2) the market for prescription drugs to treat hyperphosphatemia (*Id.* at ¶ 6); and (3) the U.S. market for treating

hyperphosphatemia (*Id.* at ¶ 52). Third, Nabi argues that Roxane fails to plead that Nabi has a “realistic probability” of achieving monopoly power. Fourth, Nabi argues that Roxane fails to plead antitrust injury because it has not identified its intention and preparedness to enter the relevant market. Fifth, Nabi argues that Roxane has failed to plead facts to show a causal relationship between the alleged antitrust violation and the alleged injury to Roxane.

In response, Roxane first contends that it has pled that Nabi has a dangerous probability of achieving monopoly power. Roxane cites the following:

On information and belief, Nabi has a dangerous probability of succeeding in its efforts to use baseless patent litigation to keep a competitor from entering the relevant markets upon the expiration of the 105 patent in order to retain and/or obtain monopoly power so as to foreclose competition, gain an illegal competitive advantage, and attempt to harm a competitor in the market for calcium acetate capsules used to treat hyperphosphatemia.

(*Counterclaim* at ¶ 53).

Second, Roxane contends that its pleading as to the relevant market is not inconsistent because it has pled, in the alternative, several different putative markets, as permitted by Fed. R. Civ. P. 8(e)(2). The Court agrees that Roxane’s pleading is sufficient<sup>3</sup>. As to pleading that Nabi has a realistic probability of achieving monopoly power, Roxane alleges:

Nabi currently has a monopoly on the sale of calcium acetate capsules, a pharmaceutical compound used to treat a condition called hyperphosphatemia, or excess phosphorous retention, which usually results from chronic kidney failure. Nabi’s monopoly has depended on its alleged rights under U.S. Patent No. 4,870,105 (the 105 patent). Upon information and belief, Nabi obtained the 105 patent from Braintree Laboratories (“Braintree”), the original assignee of the 105 patent. Nabi’s calcium acetate capsules are marketed under the trade name

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<sup>3</sup>It appears to the Court that Nabi’s true contention lies in the ability of Roxane to succeed on its allegations. At this stage of the action, ultimate success on the merits is not the issue; rather, the Court simply considers whether Roxane has pled the requisite elements of a claim for attempted monopolization.

PhosLo. The term of the 105 patent expires on April 7, 2007, presumptively ending Nabi's monopoly on the sale of calcium acetate capsules for the treatment of hyperphosphatemia.

Nabi also possesses power in a more broadly defined market - prescription drugs indicated for the treatment of hyperphosphatemia. By its own estimation, Nabi holds the market lead for the sale of such drugs with at least a 48% market share.

A nationwide product market exists within the United States for the sale of calcium acetate capsules to treat hyperphosphatemia and/or the market for drugs indicated to treat hyperphosphatemia. Aided by high barriers to entry, Nabi has market power in this product market as demonstrated by, *inter alia*, its substantial share of the relevant market(s) and its attempts to utilize baseless litigation to foreclose competition from competitive products upon the expiration of the 105 patent.

(*Id.* at ¶¶ 5-6, 50). The Court finds the foregoing allegations sufficient for claiming that Nabi has a realistic probability of achieving monopoly power. Contrary to Nabi's argument, Roxane's allegation is not simply that the 105 patent gives Nabi monopoly power; rather, Roxane alleges that Nabi attempts to foreclose competitors from the market upon expiration of the 105 patent.

With respect to antitrust injury, Roxane alleges injury by virtue of Nabi's "substantial share of the relevant market(s) and its attempts to utilize baseless litigation to foreclose competition from competitive products upon the expiration of the 105 patent." (*Id.* at ¶ 50). Roxane also alleges that Nabi will "retain and/or obtain monopoly power so as to foreclose competition, gain an illegal competitive advantage, and attempt to harm a competitor in the market for calcium acetate capsules used to treat hyperphosphatemia." (*Id.* at ¶ 53). Roxane's allegations of Nabi's alleged attempts to keep competitors from the market is sufficient for an allegation of antitrust injury. Contrary to Nabi's assertion, Roxane alleges more than simply injury to its own business.

As for Nabi's contention that Roxane has failed to plead injury in fact, Roxane maintains

that it has sufficiently pled its intention and preparedness to enter the market. In particular, Roxane alleges that it filed an ANDA with the FDA seeking approval to a generic version of calcium acetate capsules and that it intends to market the same once the 105 patent expires. (*Counterclaim* at ¶¶ 8, 10). Roxane further alleges that Nabi's purpose in bringing this action is to prevent Roxane from entering the market by arguing that the 665 and 445 patents will be infringed. (*Id.* at ¶ 17). The Court finds these allegations sufficient to claim both intention and preparedness to enter the market. See *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001).

Finally, with respect to the causal relationship between the alleged antitrust violation and injury, Roxane alleges the needless expenditure of time, effort and money in defending itself in the instant action as well as the exclusion from the market. (*Counterclaim* at ¶¶ 52-54). The Court finds Roxane's allegations sufficient for purposes of pleading "both an injury-in-fact to [claimant's] 'business or property' and a causal connection between that injury and the defendant's allegedly illegal acts." *Hecht v. Pro-Football, Inc.*, 570 F.2d 982, 987 (D.C. Cir. 1977). Further, to the extent Nabi argues that Roxane is unable to show injury because it has not yet secured approval of its ANDA, the Court rejects the same. In the Court's view, the fact that the ANDA is pending, but not approved, should not prevent a generic drug manufacturer from alleging antitrust injury. See *Bristol-Myers Squibb v. Ben Venue Lab.*, 90 F.Supp.2d 540, 545 (D. N.J. 2000) (holding that generic competitor defending patent infringement lawsuits could pursue antitrust injury although it had not received tentative FDA approval)<sup>4</sup>.

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<sup>4</sup>The Court notes that the Hatch-Waxman provides that, during the ensuing patent litigation, FDA consideration and approval of the generic ANDA will be stayed for thirty months from the date the notice of non-infringement is sent, or until a final, non-appealable determination regarding the invalidity of the

In sum, the Court finds that Roxane's counterclaim for attempted monopolization survives Nabi's Rule 12(b)(6) motion.

**B. Requests to Sever and Stay.**

Nabi requests that Roxane's antitrust counterclaim be severed from the issues of patent infringement and that discovery on the counterclaim be stayed. If the counterclaim is not severed, Nabi requests at least a four month extension of the discovery and dispositive motion deadline in order to allow time for discovery on the counterclaim. Roxane opposes Nabi's requests contending that the patent and antitrust issues substantially overlap.

The Court notes at the outset that the Magistrate Judge has had extensive dealings with the parties in this case as discovery has progressed. On October 20, 2006, Judge Kemp issued an Order addressing Nabi's present request to sever Roxane's counterclaim and stay discovery on the issues. Judge Kemp has advised the parties that whether severance would occur is a decision for the District Court. If severance is denied, Judge Kemp concluded that a stay of discovery was not warranted. (Doc. #64). The undersigned now concludes that severance of the antitrust counterclaim is not appropriate. In the Court's view, the issues surrounding the counterclaim, in particular the exceptions to *Noerr-Pennington* immunity discussed above, overlap with issues as to alleged infringement of the 665 and 445 patents. Thus, the Court finds no reason to sever Roxane's counterclaim. In turn, the Court declines to issue a four month stay of the current discovery schedule. Magistrate Judge Kemp has directed that discovery on the counterclaim proceed with the other discovery in this case. Thus, the Court finds no reason to extend the

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patent is entered, whichever date is earlier. See 21 U.S.C. § 355(j)(5)(B)(iii)


present deadline. The parties shall adhere to the schedule set by the Magistrate Judge.

**IV.**

In light of the foregoing, Plaintiff's Motion to Dismiss Defendant's Counterclaim or, in the alternative, to Sever and Stay (**Doc. #47**) is **DENIED**. The Clerk shall remove this motion from the Court's pending motions list.

**IT IS SO ORDERED.**

3-21-2007  
**DATE**

  
**EDMUND A. SARGUS, JR.**  
**UNITED STATES DISTRICT JUDGE**